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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,692	07/09/2003	Jodi Nelson	47-00B	1639

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,692	NELSON, JODI	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17NOV2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *14-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/4; 6/10/5*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS: 6/27/5; 9/20/5; 12/12/5*.

DETAILED ACTION

Status of Claims

1. Claims 1-36 are pending.

2. Claims 1-13 are elected and rejected as per the election responses of November 17, 2005.

3. Claims 14-36 are nonelected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of the Group II, corresponding to claims 1-13, of and the election of species by applicants of November 17, 2005 for the quinoline species of chloroquine phosphate and the adjuvant species of cimetidine as well as the method of treating the elected condition/disease of drug-induced dyskinesias are acknowledged. The traversal is on the ground(s) that the two groups should be examined together. This is not found persuasive because the method of use claims could be practiced with another materially distinct compound, such as L-Dopa and vitamin B_{12}. In addition, the inventions of the separate and distinct methods of Groups II-V is still maintained because, for example, a method of treating a movement disorder, such as Dyskinesia or Parkinson's disease, would require different functions and effects than treating, for example, thalamic hypersensitivity or reducing apoptosis.

5. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

6. The information disclosure statement filed August 24, 2004 (24 sheets) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Please refer to those citations that were not considered as indicated on the 1449 with a strikethrough.

7. The information disclosure statements filed on June 10, 2005 (1 sheet); June 27, 2005 (2 sheets); September 20, 2005 (1 sheet); and December 12, 2005 (2 sheets) have been reviewed and considered, see enclosed copies of PTO FORMs 1449.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. *Regents of the University of California v. Eli Lilly & Co.., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S.Ct. 1548 (1980),* holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly, 119 F.3d at 1566.* The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for *Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001)*, which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...." *Enzo Biochem, Inc. v. Gen-Probe., 296 F.3d, 316, 1324-25 (Fed. Cir. 2002)* (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y 2003).*

11. There is insufficient descriptive support for the ensuing phrase, "peripheral metabolism inhibitor." In addition, the instant specification does not describe what is meant by the phrase, "peripheral metabolism inhibitor." Structural identifying characteristics of the phrase, "peripheral metabolism inhibitor." There is no evidence that there is any per se structure/function relationship between the phrase, "peripheral

metabolism inhibitor." The instant specification does not provide an adequate written description for the phrase, "peripheral metabolism inhibitor." In addition these terms are described illustratively in the instant specification. In fact, there is only an adequate written description for the combined administration of the "peripheral metabolism inhibitor as adequately described in claim 4. Accordingly, these claims fail to comply with the written description requirement.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 9 recites the limitation "said movement disorder" in line 1 of claim 9. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not specifically utilize the language of the limitation "said movement disorder."

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts-Lewis et al. of U.S. Patent No. 5,430,039 in view of Di Rocco et al. of U.S. Patent No. 5,496,836. Roberts-Lewis et al. teach it is known in the neurological art of pharmacology that chloroquine or hydroxychloroquine are used in the treatment of neurological disorders, namely Parkinson's disease, (see column 2, lines 22-34 and column 8, lines 40-60). Di Rocco et al. teach of treating movement disorders, such as Parkinson's disease, with the administration of cimetidine, (see column 5, lines 20-45 and from column 6, line 23 to column 7, line 11). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Moreover, it is well within the level of the skilled artisan to determine optimal modes and methods of administration as well as the procedures for making

pharmaceutical compositions having the optimum therapeutic dosage while minimizing adverse and/or unwanted side effects.

18. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bussy, R. K., Editor-in-Chief, Merritt's Textbook of Neurology, Ninth Edition, pages 713-730 in view of Lim, L. Y. et al. of Clinical and Experimental Pharmacology & Physiology 12, 527-531, 1985 in further view of Di Rocco et al. of U.S. Patent No. 5,496,836. Bussy, R. K. teach of treating parkinsonian syndromes, namely Parkinson's disease and drug-induced Parkinsonism, which are movement disorders, (see page 713-716 and 727-730). In addition, Bussy, R. K. teach of various therapeutic treatments for Parkinson Disease, namely anticholinergics, antihistamines, and antidepressants, including serotonin-uptake inhibitors, (see page 722), which provides the skilled artisan with motivation to utilize various types of compounds to treat parkinsonian syndromes, namely Parkinson's disease and drug-induced Parkinsonism. Lim et al. teach that compounds possessing the quinoline nucleus, including chloroquine, have long been associated with anticholinergic activity, (see page 527). Moreover, Lim, L. Y. et al. provide the skilled artisan with the notion that compounds possessing the quinoline nucleus, including chloroquine, have long been associated with anticholinergic activity. Di Rocco et al. teach of treating movement disorders, such as Parkinson's disease, with the administration of cimetidine, (see column 5, lines 20-45 and from column 6, line 23 to column 7, line 11). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them

flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Moreover, it is well within the level of the skilled artisan to determine optimal modes and methods of administration as well as the procedures for making pharmaceutical compositions having the optimum therapeutic dosage while minimizing adverse and/or unwanted side effects.

Obviousness-type Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. In addition, if rejoinder of method claims 40-45 of copending application 10/192,414 is granted then instant claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 44 and 45 of copending Application No. 10/192,414. Both the instant claims as well as claim 44 and 45 of copending Application No. 10/192,414 teach of treating an ailment with a composition of a quinoline compound with a peripheral metabolism

inhibitor. It is well within the purview of the skilled artisan to determine optimum amounts and modes and methods of administration as well as preparation that have therapeutic effects while minimizing adverse or unwanted side effects.

21. This is a provisional obviousness-type double patenting rejection, provided that claims method claims 40-45 of copending application 10/192,414 is granted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

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DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
February 21, 2006